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| APPLICATION NO.                                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/663,530  | 09/15/2003  | Chi-Tang Ho          | RU-0177-CON         | 3585             |
| 20583   | 7590        | 08/11/2005           | EXAMINER            |                  |
| JONES DAY<br>222 EAST 41ST ST<br>NEW YORK, NY 10017 |             |                      | WARE, DEBORAH K     |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1651                |                  |

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/663,530

Applicant(s)

HO ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 10-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 10-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Claims 1 and 10-36 are presented for examination on the merits.

***Response to Amendment***

The prior rejection has been removed and thus arguments are considered moot. The amendment has been entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 13-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. A method for preventing cancer by administering to an animal an effective amount of a composition of as claimed to prevent cancer is not clearly enabled. There would be undue burden of experimentation for one of skill in the art to practice the claimed method for preventing cancer because the exemplified disclosure does not provide guidance for which one of skill to carry out for prevention of cancer.

There are no examples which show prevention of cancer is provided by inducing phosphorylation of Bcl-2 with the extract or with the compound isolated from the extract. Also to carry out prevention without undue burden of experimentation one of skill would have to be provided with the dosages and amounts required to induce phosphorylation in vivo for which to achieve prevention; and furthermore, the mode of administering for prevention is not clearly

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described for preventing cancer. There is a difference between preventing cancer and treating the cancer.

Thus, Applicants have not met the burden of undue experimentation for prevention of cancer. The level of unpredictability is high in the biological arts and one of skill may not be able to predict which cells will be induced to die off, of these cells not all may be cancerous cells. In other words, it is unpredictable in the art to determine whether all would be cancerous cells which would be necessary for cancer to be prevented as claimed. If all the cancerous cells are not prevented then cancer is not prevented because some cells will remain and cancerous cells can spread in vivo. Although extrapolations of effective doses may be routine in the art at the level of determining appropriate treatment doses it is unpredictable and undue burden of experimentation in the art to determine the same for the prevention of cancer of which adequate cure and prevention has not been routine in the art. Therefore, the claim directed to a method for preventing cancer is not deemed enabled. a rejected base claim for reasons noted above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 10-36 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 99/43314 (Shaikenov et al.) cited on enclosed PTO-892 Form.

Claims are drawn to methods for preventing or treating cancer in an animal comprising administering to an animal an effective amount of the composition of an extract of *Inula britannica*.

Shaikenov et al. teach a composition comprising an extract of *Inula Britannica* or compounds isolated therefrom comprising sesquiterpene lactone. Note 19, lines 15-21 and page 23, lines 12-25. Further, a method for preventing or treating cancer in an animal comprising administering to an animal an effective amount of the composition is also disclosed. See the abstract and page 23, lines 20-27.

The claims are identical to the disclosure of Shaikenov et al. and are therefore, considered to be clearly anticipated by the teachings therein.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 10-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO patent as cited above in view of Zhou et al., cited on the enclosed PTO-892 Form .

This claims are discussed above and are further drawn to 1-O-acetylbritannilactone or 1,6-O,O-diacetylbritannilactone.

Shaikenov et al. teach a composition comprising an extract of *Inula Britannica* or compounds isolated therefrom comprising sesquiterpene lactone. Note 19, lines 15-21 and page 23, lines 12-25. Further, a method for preventing or treating cancer in an animal comprising administering to an animal an effective amount of the composition is also disclosed. See the abstract and page 23, lines 20-27.

Zhou et al. clearly teach 1-O-acetylbritannilactone or 1,6-O,O-diacetylbritannilactone which are isolated from *I. britannica*.

The claim differs from the teaching of the cited patent in that the specific compounds as noted above are not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was filed to provide for a methods as disclosed by the cited patent comprising 1-O-acetylbritannilactone or 1,6-O,O-diacetylbritannilactone as disclosed by Zhou et al. because these selected compounds are also disclosed to be isolatable from *I. Britannica* extracts, note page 249, col. 1, all lines. Clearly one of skill would have been motivated to select for these two lactones as well since sesquiterpene lactones from *I. Britannica* are clearly disclosed by the primary reference to be comprised in compositions

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formed from plant extracts of *I. Britannica*. To select for various concentrations and amounts thereof is well within the purview of an ordinary artisan. In the absence of persuasive evidence to the contrary the claim is deemed *prima facie* obvious over the cited prior art combination. The two selected lactones are well known and to select for one or the other of these two lactones is well within the purview of an ordinary artisan, especially since they are disclosed to possess cytotoxic activity.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 10-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-6 of U.S. Patent No. 6,627,623. Although the conflicting claims are not identical, they are not patentably distinct from each other because the identical compounds are found in the *Inula Britannica* extract and used in a method of treating cancer.

The claims of the instant case would have been obvious over the patented claims based on the similar scope of the claimed subject matter. One of skill would have been motivated to

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administer the compound for a method of remedying cancer. Claims are therefore, obvious over the patented claims.

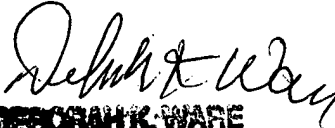
All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924.

The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0927. The fax phone numbers for the organization is 571-273-8300.

  
**DEBORAH K. WARE**  
**PATENT EXAMINER**

Deborah K. Ware  
1651  
July 23, 2005